UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,833	08/25/2003	Max Kelly	11757.44USI1	2869

7590 03/22/2004

Mark T. Skoog
MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, MN 55402-0903

EXAMINER	
STUCKER, JEFFREY J	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/647,833	KELLY ET AL.	
	Examiner	Art Unit	
	Jeffrey Stucker	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-17 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 112403.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 and 8-17 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant specification lacks a written description of, and enablement for, making and using any individual phage that is 99% effective against *Staphylococcus aureus*.

There is no disclosure of the particular strains of *S. aureus* used to determine the effectiveness of any given phage. One of skill in the art, even though the level of skill is high, would have an undue burden trying to determine if a phage has the same lytic effective as required for the claimed method because a specific reference panel has not been disclosed. The specification teaches that strains of *S. aureus* from Ontario, Canada, were used but the specific isolates were not set forth. The apparent activity of the phage would change, not necessarily by the particular phage, but by the particular isolates that are used in testing. See, for example, Pantucek et al. (Virology, 1998), first line of the abstract ("95% of culture collection and hospital strains", and "43% of culture collection strains") and page 244, Table 2, teach that the Φ812 phage has differing levels of lytic activity depending upon the panel of *S. aureus* strains tested. The description of the claimed phage is not that of the phage but of the susceptibility of a variable panel of *S. aureus* isolates. Therefore, it is not clear how one is to know if the phage is capable of

lysing about 99% of MRSA stains. The strains could vary as new isolates are found or mutated, and hence, the benchmark is not fixed. At what point would one set the standard? The composition of the claimed invention would change with each different batch of *Staphylococcus aureus* tested.

The specification does not describe or support a method for treating a disease with an individual phage that has 99% lytic activity against *S. aureus*. The data presented in the specification on the table on page 9 shows only 88% strong susceptibility against a collection of *S. aureus* from Ontario. This is not all strains of MRSA or representative of all MRSA. Thus, there is no support for a method that uses a phage that is 99% lytic to MRSA.

The specification is objected to, and claims 1-17 are rejected, under 35 U.S.C. §112, first paragraph, as failing to provide an adequate teachings of enablement and failing to provide a best mode of carrying out the invention.

The bacteriophages are biological materials necessary to practice the claimed invention as the starting material and the product claimed per se in claims are necessary to practice the invention. Because it does not appear that the bacteriophages are known and publicly available or can be reproducibly isolated from nature without undue experimentation, deposit of the bacteriophages is required. Without a publicly available deposit of the bacteriophages, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of the bacteriophages may be an unpredictable event. Mere description of the bacteriophages is not adequate, due to its taxonomic incompleteness and inexactness. Note that the best mode is not satisfied by

a written disclosure unless that exact embodiment is absolutely reproducible from that disclosure. If reproducibility of the bacteriophages is not established, failure to deposit the bacteriophages would result in the quality of applicant's best mode disclosure to be so poor as to effectively result in concealment of the best mode contemplated by applicant for carrying out the invention. *In re Sherwood*, 615 F.2d 809, 204 USPQ 537 (CCPA 1980). Applicant is reminded that the deposit of biological material is a recognized exception to the requirement for a written disclosure only where applicant was unaware of repeatable process to obtain this material at the time the application was filed.

The specification lacks complete deposit information for the deposit. Applicant's referral to receiving the bacteriophages at page 8 of the specification is an insufficient assurance that all required deposits have been made and the conditions of 37 CFR 1.801-1.809 met.

If deposits have been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicants, assignees or a statement by an attorney of record over his or her signature and registration number stating that each deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to each deposits will be irrevocably removed upon the grant of a patent on this application and that each deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As a possible means for completing the record,

applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If deposits have not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR 1.801-1.809 regarding availability and permanency of deposits for U.S. patent purposes, assurance of compliance is required. Such assurance may be in the form of an affidavit or declaration by applicant or assignees or in the form of a statement by an attorney of record who has authority and control over the conditions of deposit, over his or her signature and registration number, averring:

(a) during the pendency of this application, access to each deposit will be afforded to the Commissioner upon request:

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

(c) each deposit will be maintained in a public depository for a period of at least thirty years form the date of deposit or for the enforceable life of the patent or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) each deposit will be replaced if it should become nonviable or non-replicable.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the

various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1-11, 13, and 14 are rejected under 35 U.S.C. § 103(a) as obvious over Merril et al. (PNAS, 1996) in view of Pantucek et al. (Virology, 1998).

Merril et al. teach the use of a bacteriophage as antibacterial agents for treatment. The reference does not teach the specifically claimed strains of phages. See entire reference.

Pantucek et al. disclose that bacteriophage Φ812 was known in the art prior to the instant invention, see the entire reference, particularly, page 242, first column. They teach that it is lytic for a wide variety of *Staphylococcus aureus* strains. See the first line of the abstract and Tables 1-3. It is in a buffer which can be considered to be a suitable pharmaceutical formulation.

Thus, the instant invention is obvious over Merril et al. in view of Pantucek et al.

Claims 12 and 15 are rejected under 35 U.S.C. § 103(a) as obvious over Pantucek et al. (Virology, 1998) in view of Day et al (GB 2 253 859A).

The relevance of Pantucek et al. has been given above.

Day et al. teach applying bacteriophages to foodstuff to kill harmful bacterial. See entire reference.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the phage taught by Pantucek et al. into the method of Day et al. with the expectation of inhibiting a serious pathogen, *Staphylococcus aureus* strains, in food. One would been motivated to do this to make food safer. Thus, the instant invention is obvious of Pantucek et al. in view of Day et al.

Claims 16 and 17 are rejected under 35 U.S.C. § 103(a) as obvious over Merril et al. (PNAS, 1996) in view of Pantucek et al. (Virology, 1998).

Merril et al. nor Pantucek et al. teach adding an antibiotic to the formulation. However, antibiotics are so well known as to be a household word and are admittedly known. See page 5, lines 4-11 of the instant specification. It would have been obvious to one of ordinary skill in the art at the time the invention was made to add a well known antibacterial composition such as an antibiotic to a pharmaceutical composition with the expectation that it would have at least an additive effect on the action of the phage, thereby increasing the effectiveness of the formulation. Therefore, it would have obvious to add an antibiotic the phage of Pantucek et al.

No claims are allowed.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

The Group 1600 Official Fax number is: (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Stucker whose telephone number is (571)-272-0911. The examiner can normally be reached Monday to Thursday from 7:00am-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571)-272-0902.

Jeffrey Stucker

JEFFREY STUCKER
PRIMARY EXAMINER